

## **REMARKS**

The present Office Action addresses and rejects claims 1-9 and 11-13. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

### ***Amendments to the Claims***

Applicants amend claims 1, 5, and 9 to clarify that the bioabsorbable lubricating coatings reduce device drag between the first and second contact surfaces of the device. Support for these amendments can be found throughout the specification, for example at paragraph [0039] of the published application. Applicants also amend claim 9 to correct a typographical error (see claims as presented in February 20, 2007 Amendment and Response). No new matter is added.

### ***Rejections Pursuant to 35 U.S.C. §103***

Claims 1-9 and 11-13 stand rejected pursuant to 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,846,313 to Rogers et al. ("Rogers") in view of U.S. Patent No. 6,197,320 to Shalaby ("Shalaby"). Independent claims 1, 5, and 9 each recite a bioabsorbable medical device having a *bioabsorbable lubricating coating* disposed on at least a portion thereof. Claims 1, 5, and 9 also recite that the coating reduces *device drag* between the contact surfaces of the device. The Examiner continues to assert that Rogers teaches the claimed invention except for the lubricating coating claimed by Applicants. Since Applicants succeeded in overcoming earlier obviousness rejections, the Examiner now relies on a different secondary reference to teach this feature, once again arguing that it would have been obvious to modify the device of Rogers to include a lubricating coating, this time as taught by Shalaby. Applicants respectfully disagree. Taken alone or in combination, the references fail to teach or suggest the claimed invention.

At the outset, Rogers fails to teach or suggest a coating disposed on at least a portion of the device. Indeed, the Examiner acknowledges that Rogers fails to disclose the claimed bioabsorbable lubricating coating and asserts that Rogers teaches "a dye." In an attempt to make this rejection appear to be more plausible, the Examiner implies that the dye taught by Rogers is a coating. This implication is incorrect. The dye disclosed by Rogers is *not a coating*. Rather, the dye, as is well known, is merely added to the polymer material during processing "in order to make it more visible

in the surgical field.” (Rogers at Col. 8, lines 27-29) As explained at column 7, lines 4-52, the manufacturing process of the device disclosed by Rogers involves blending polymer components at high temperatures, grinding the resulting polymer blend, and then injection molding the polymer blend to produce the desired device. The dye, which Rogers teaches is “added during processing,” would necessarily be combined with the polymers at some point during this manufacturing process. Thus, the dye would be melted and molded along with the polymers and therefore dispersed throughout the resulting polymer device. It clearly is not in any way a coating. Coatings in general, and as taught by Applicants, are applied to the surface of a device and are not present throughout a device as a dye would be. (See, e.g., paragraph 0040) Therefore, the dye taught by Rogers is not a coating, much less a bioabsorbable lubricating coating applied to reduce device drag between contact surfaces of a device. The failure of Rogers to disclose any coating renders it completely deficient as a reference.

Shalaby fails to remedy the deficiencies of Rogers because Shalaby fails to teach or suggest a coating that provides reduced device drag between contact surfaces of a device, as recited by claims 1, 5, and 9. In general Shalaby is concerned with surface coatings on surgical sutures to “improve their handling and knotting characteristics.” (Shalaby at Col. 1, lines 20-23) Although Shalaby discloses that these coating solutions can also have uses as “absorbable lubricious coatings,” there is simply no teaching or suggestion in Shalaby to use the coatings to reduce device drag between contact surfaces of a device. (Shalaby at Col. 7, lines 18-19) To the contrary, Shalaby only discloses the use of coatings on devices that, without exception, pass into or through tissue. Such devices include trocars, catheters, syringes, etc. (See Shalaby at Col. 7, lines 18-27) Shalaby does not disclose that the “lubricious coatings” reduce friction between contact surfaces of a device (i.e., device drag) or even that the “lubricious coatings” reduce friction between the device and tissue (i.e., tissue drag). The fact remains, however, that there is no teaching or suggestion in Shalaby to apply the coatings to devices to reduce friction between different contact surfaces of the devices themselves. Therefore, in light of the deficiencies in the teachings of both Rogers and Shalaby, the combination would fail to teach or suggest the claimed invention.

Moreover, the Examiner has not only disregarded the deficiencies in the references, but has also failed to provide a valid reason to combine Rogers and Shalaby. The Examiner states that the motivation or rationale for the combination would be “for tissue regeneration and to decrease friction during operation of the device.” However, if one of ordinary skill in the art were to rely on the

teachings of Shalaby to modify the nonexistent coating of Rogers according to the reason suggested by the Examiner, presumably the coating would be applied to the outer tissue contacting surfaces of the rivet 3, not to the pin 5 or the interior surfaces of the rivet. Therefore, even if Rogers were modified in view of the teachings of Shalaby according to the reason provided by the Examiner, the combination would not result in the claimed invention.

The proposed combination of references is legally impermissible for additional reasons. In accordance with MPEP § 2141(II)(B), "[t]he references must be considered as a whole and *must suggest the desirability* and thus the obviousness of making the combination." (Emphasis added.) In fact, neither reference teaches or suggests the desirability of the claimed coating between different contact surfaces. (See MPEP § 2141(II)(B)) Indeed, one skilled in the art would not be motivated to apply any sort lubricious coating to the different contact surfaces of Rogers because such a coating might be expected to render the device unsatisfactory for its intended purpose. In particular, the pin 5 taught by Rogers relies on friction between itself and the internal passage 14 in the rivet 4 to prevent the pin from simply being pushed back out of the rivet 4 after insertion. If a coating were applied to reduce friction between the contact surfaces of the rivet 4 and the pin 5, one of ordinary skill in the art might fear that the pin 4 could simply slip out of the rivet 5. Thus, although the Examiner has provided a potential reason to combine the references, it is a reason that is unsupported by the teachings of the references, and it fails the "predictability" test articulated by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007) and articulated in the PTO Examination Guidelines issued in response to *KSR*.

Finally, in order to make out an obviousness rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art to the claims. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds *cannot be sustained by mere conclusory statements*; instead, there *must be some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness") (emphasis added). Without providing reasoning with some rational underpinning, the Examiner easily falls prey to improper hindsight reasoning:

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use

of hindsight'"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, the Examiner has provided references that, when combined, would not result in the claimed invention. More suspiciously, neither reference supports the rationale advanced by the Examiner, instead the rationale seems similar to that described in Applicant's specification. (See published application at Paragraph 0012 where Applicant notes that the reduction of device drag is desirable.) This gives the appearance of the very essence of hindsight. Without benefit of Applicants' disclosure, one of ordinary skill in the art relying on the disclosures of Rogers and Shalaby would simply not consider the problem of device drag. It is only with the benefit of Applicants' disclosure that the Examiner is able to identify device drag as a problem. One of ordinary skill in the art would therefore have had no reason to look at Rogers, which fails to even disclose a coating, and then look to the teachings of Shalaby, to provide a coating to reduce device drag between different contact surfaces.

Accordingly, independent claims 1, 5, and 9, as well as claims 2-4, 6-8, and 11-13 which depend directly or indirectly therefrom distinguish over Rogers and Shalaby, taken alone or combined, and represent allowable subject matter.

### ***Conclusion***

In view of the foregoing, Applicants submit that all previously submitted claims, as amended, are now in condition for allowance, and allowance thereof is respectfully requested. Examiner Philogene is urged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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